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Report of the Strategic Advisory Group of Experts (SAGE)

Geneva, 14-15 June 2001



DEPARTMENT OF VACCINES AND BIOLOGICALS



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Abbreviations

AD auto-disable (syringe)

ADC accelerated disease control

AFP acute flaccid paralysis

AFRO WHO Regional Office for Africa

AVI accelerated vaccine introduction (priority project)

BCG bacillus Calmette-Guérin (vaccine)
BSE bovine spongiform encephalopathy

CDC Centers for Disease Control and Prevention (USA)

CJD Creutzfeldt-Jakob disease

DFID Department for International Development (UK)

DTP diphtheria-tetanus-pertussis (vaccine)

ECBS Expert Committee on Biological Standardization (WHO)
EMRO WHO Regional Office for the Eastern Mediterranean

EPI Expanded Programme on Immunization

GACVS Global Advisory Committee on Vaccine Safety
GAVI Global Alliance for Vaccines and Immunization

HBV hepatitis B virus

HepB hepatitis B (vaccine)

Hib Haemophilus influenzae type B
ICC interagency coordinating committee
ICG International Coordinating Group

IEC information, education and communication (materials)

IMCI integrated management of childhood illnesses

IPV inactivated polio vaccine

IUATLD International Union against Tuberculosis and Lung Disease

IVR Initiative for Vaccine Research

MMF macrophagic myofascitis

MNT maternal and neonatal tetanus
MVP Meningitis Vaccine Programme

NID national immunization day
NRA national regulatory authority

NT neonatal tetanus
OPV oral polio vaccine

PAHO Pan American Health Organization

PATH Program for Appropriate Technology in Health

SAGE Strategic Advisory Group of Experts

TCG Global Technical Consultative Group for Poliomyelitis Eradication

TSE transmissible spongiform encephalopathy

TT tetanus toxoid

UNF United Nations Foundation

UNFPA United Nations Population Fund

UNGASS Special Session of the United Nations General Assembly

UNICEF United Nations Children's Fund

V&B Department of Vaccines and Biologicals (WHO)

VVM vaccine vial monitor

WHA World Health Assembly

Executive summary

Introduction

The Strategic Advisory Group of Experts (SAGE), established by the Director-General of WHO in 1999 to provide guidance on vaccines and biologicals, held its third annual meeting on 14 and 15 June 2001 in Geneva, Switzerland.

Progress was reviewed in relation to various objectives and targets set by the Department of Vaccines and Biologicals (V&B). In his opening address, Dr Yasuhiro Suzuki, Executive Director of WHO's Health Technology and Pharmaceuticals cluster, pointed out that guidance from SAGE would be critical as WHO began reviewing and revising the strategic plan covering vaccines, immunization and biologicals for 2002–2005. The Director of V&B, Dr Bjørn Melgaard, outlined the dramatic changes that had transformed the global immunization scene in the preceding year and the issues that SAGE would address. Important among these were:

- how the Global Alliance for Vaccines and Immunization (GAVI) would come to terms with a possible new mandate as an alliance for the whole global immunization agenda;
- · how to close the polio funding gap;
- how to align the objectives of GAVI with polio eradication and other disease control objectives;
- how to strive towards equity in immunization by achieving access and high coverage throughout the world;
- how the infusion of huge additional resources was leading to the introduction of new tools and technologies and creating a need for more partnership in vaccine research. Professor Sir Gustav Nossal, SAGE Chair, referred to the hope and dynamism that GAVI had created and to the roles of WHO, SAGE, GAVI and the Vaccine Fund.¹ He remarked that whereas GAVI was financed for five years, WHO would exist until the world was healthy enough not to need it. Furthermore, whereas the Vaccine Fund was narrowly focused, GAVI had to have a broad vision. Sir Gustav considered that the objectives of GAVI and V&B should be identical.

Formerly the Global Fund for Children's Vaccines.

The deliberations

On the first day there were three parallel sessions, covering innovation, the strengthening of immunization systems, and accelerated disease control. WHO's work, including projects conducted with UNICEF and other partners, was presented and questions were put to SAGE. For each topic of discussion a list of endorsements and recommendations was agreed by a subgroup. On the second day, summaries of the previous day's deliberations were presented to a plenary session and recommendations based on them were adopted. Additional matters, including GAVI, were discussed, and recommendations concerning them were also made. A summary of the main topics of discussion is given below, followed by the recommendations.

Main topics of discussion

Innovation

The considerable achievements of V&B in the area of innovation were noted. These included internal advocacy in many countries for the introduction of new vaccines. Some of the issues discussed are listed below. Fuller summaries are given in Section 2.

- Disease burden activities: the feasibility of estimating the *Haemophilus* influenzae type b (Hib) pneumonia burden in Asia using vaccine intervention trials.
- **Vaccine introduction**: the collection of information in order to develop a position on infantile hepatitis B (HepB) immunization for presentation to SAGE.
- Combination vaccines: a paper presented to SAGE on demand and supply issues was an excellent example of WHO's role in making critical information available to countries and decision-makers on the introduction of new vaccines.
- Initiative for Vaccine Research (IVR): a discussion of IVR's role in integrating WHO's vaccine development activities.
- Meningococcal A/C vaccine: exploring public-private partnerships, as reflected in the V&B initiative relating to the meningococcal vaccine project for Africa.
- Pneumococcal conjugate vaccines: the importance of additional efficacy studies in developing countries to determine the impact of vaccine on pneumonia and mortality.

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